

# GELATIN - Topic 2 requested by India

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# Technical background

## What is gelatin?

- natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry)

# Technical background

## The animal by-products market

MBM:	fertiliser, pet-food
MBM-fats:	oleochemistry, biodiesel, glycerine
<b>gelatin:</b>	<b>high value product</b>
Blood:	blood-meal, blood-products
Feather:	hydrolysed proteins, feed
etc...	

# Technical background

## World Production of gelatin

More than 300,000 tonnes of gelatin are produced annually (2006 figures).

Produced mainly from pig and cattle skin (74%) and bone (24%).

Used widely in the food and pharmaceutical industries.

- Edible: gelatin desserts, gummed candies, marshmallow, wine fining or clarification and prepared meat products.
- Pharmaceutical: hard and soft capsules, stabilisers for oil emulsions and glycerinated gelatin for suppositories
- Photographic: paper coating and as a component in silver halide emulsion coatings
- Technical: micro-encapsulation, bacteriological culture media and in emulsion polymerisations.
- Animal feed (but actually a rather poor source of protein) – not to ruminants?



# Technical background

## Estimates of Gelatin World Market 2003

<b>Source</b>	<b>Tonnes</b>	<b>%</b>
Pig skin	117,950	42%
Bovine hides	81,650	29%
Bones	76,750	28%
other	1,950	1%
<b>Source</b>	<b>Tonnes</b>	<b>%</b>
W Europe	117,800	42%
E Europe	4,950	2%
N America	60,500	22%
S America	43,050	15%
Asia	49,500	18%
other	2,500	1%
<b>TOTAL</b>	<b>278,300</b>	

# Technical background

## Specifications of gelatin

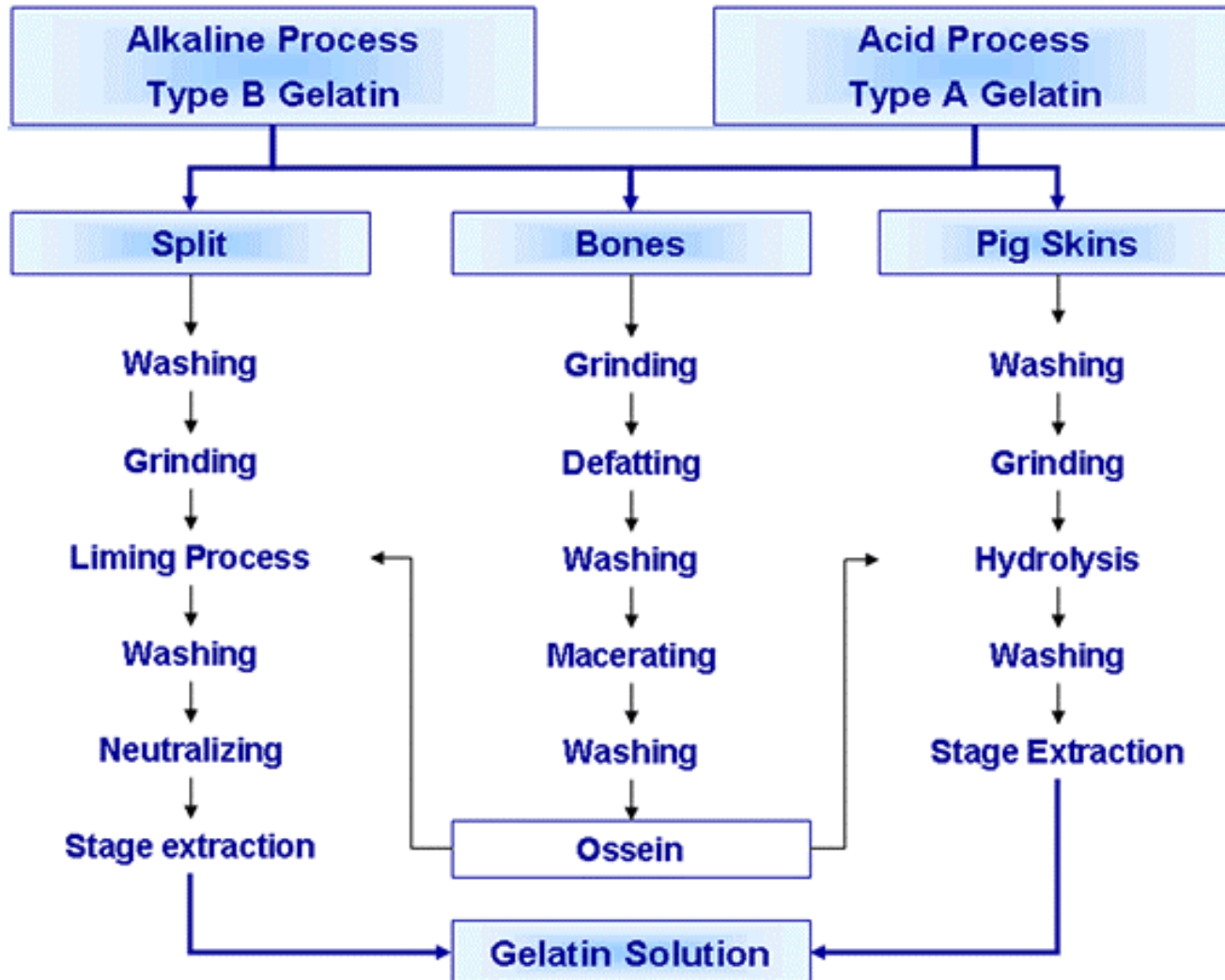
Bloom Strength - measurement of the strength of a gel formed by a 6 2/3 % solution of the gelatin, at 10 °C for 18 hours. (grades available: 50, 75, 100, 125, 150, 175, 200, 225, 250, 300 Bloom)

- A standard viscosity range is associated with each bloom level gelatin (between 10 - 2 cP for 6 2/3 % solution at 60 °C )
- Clarity
- Micro-biological evaluation, inorganic ash, clarity, moisture content and heavy metal content.

These parameters depend on raw materials, extraction step, processing techniques especially thermal treatments.



# Technical background



# Technical background

## Acid Manufacturing Process

Mainly pigskin and fish skin, sometimes bone materials.

- collagen acidified to about pH 4
- heated stepwise from 50°C to boiling to denature and solubilise the collagen
- defatted, filtered, concentrated by vacuum evaporation or membrane ultra-filtration treatment
- drying by passing air over the gel
- grinding and blending to customer requirements and packaging

The gelatin has an isoionic point of 7 to 9 based on the severity and duration of the acid processing of the collagen which causes limited hydrolysis of the asparagine and glutamine amino acid side chains.



# Technical background

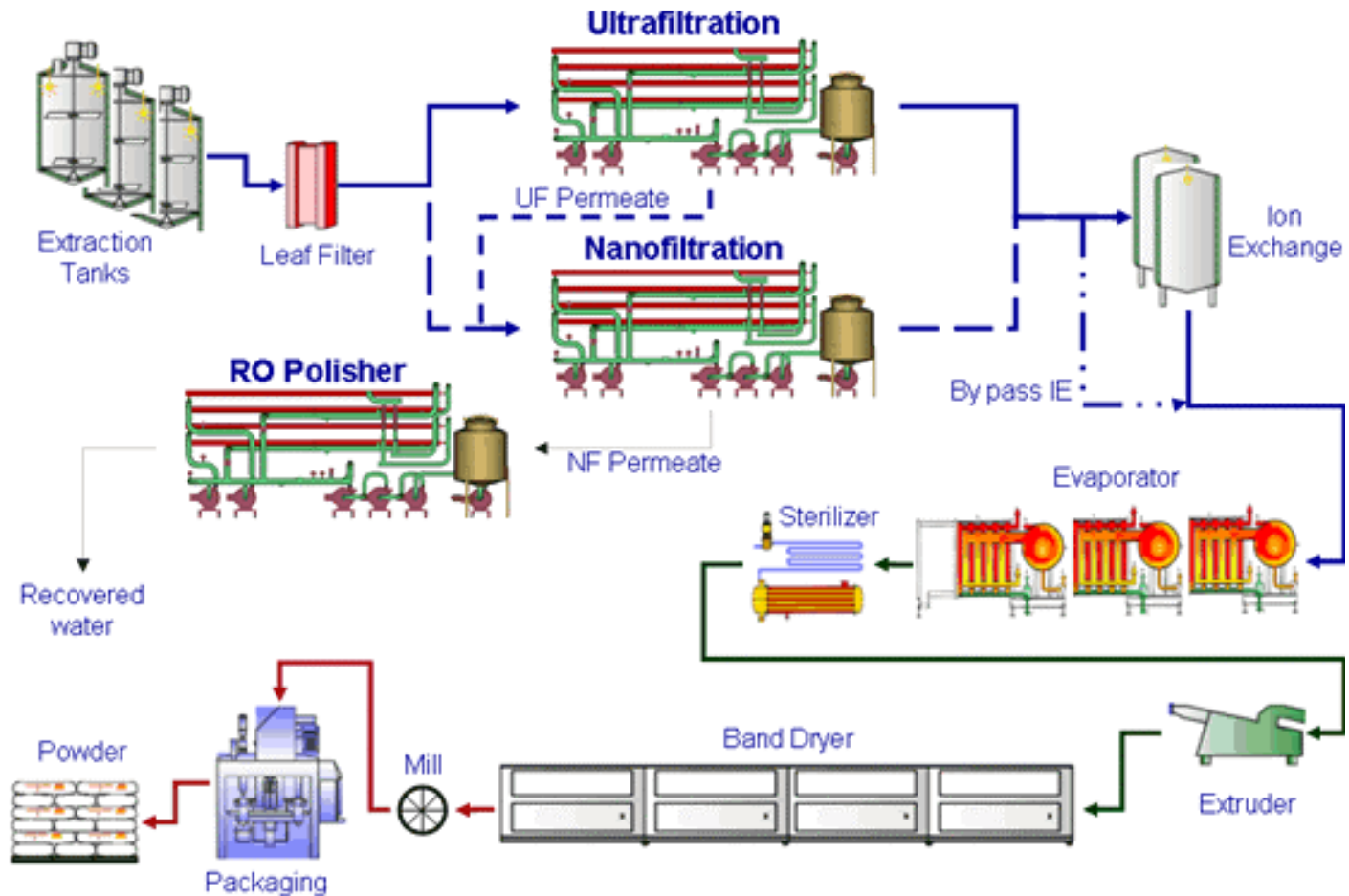
## Alkali Manufacturing Process

Mainly bovine hide and collagen sources from old animals.

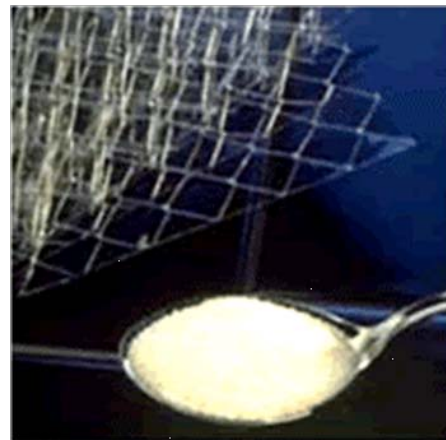
- collagen is submitted to a caustic soda or lengthy liming process [the alkali hydrolyses the asparagine and glutamine side chains to glutamic and aspartic acid and the gelatin normally has a isoionic point of 4.8 to 5.2. With shortened (7 days or less) alkali treatment, isoionic points as high as 6 are produced]
- the collagen is washed free of alkali and treated with acid
- then denatured and converted to gelatin by heating, as with the acid process
- often necessary to demineralise the gelatin solution to remove excessive amounts of salts using ion-exchange or ultrafiltration
- thereafter the process is the same as for the acid process - vacuum evaporation, filtration, gelation, drying, grinding and blending.



# Technical background



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## Uses of gelatin in food production

<b>Product</b>	<b>Gelatine conc</b>	<b>Gelatine role</b>
Capsules for food supplements and pharmaceuticals.	86%	Delivery systems
Gelly desserts	21% (dry weight)	Dessert
Protein fortified foods, cereal bars, emergency rations,	10-20%	Protein
Low fat products, e.g. whipped cream, ice cream, margarine, mayonaise	2-32%	Emulsifier, fat replacer
Sliced meat products	5%	Meat binder
Glazes for pastries, sausages meat products	20% dipping solution or spray	Reduces surface water loss
Canned and cooked meat products: e.g. corned beef	2-5%	Water binding
Dairy products e.g. Yoghurt, Curds, cream cheese, ice cream	1%	Prevent water loss
Finings for fruit juices and wines	0.01%	Clarifying

# Technical background

While India enjoyed OIE (1999) BSE Risk Status level 1 (free) it had some advantage over other sources for the export of gelatin and bones, hides and collagen for gelatin production.



# TSE risks of gelatin

Updated opinion on  
The safety with regard to TSE risks of gelatin  
derived from ruminant bones or hides  
Adopted by the Scientific Steering Committee  
March 2003

# TSE risks of gelatin

## Questions regarding the safety of gelatin produced from ruminant material

- Can gelatin produced from ruminant bones or hides be considered to be free of TSE infectivity?

If not

- Under which condition of sourcing of the material (geographical origin, animal origin, type of tissue) and/or age of the animal and/or production process, can it be considered as safe?

# TSE risks of gelatin

## **Three major factors that influence the risk of exposure from animal by-products in relation to BSE**

1. The titre of infectivity likely to be found in the tissue used in its manufacture. This is directly linked to the source of tissue and animal.
2. The effectiveness of the process used for the inactivation (or the elimination) of the agent.
3. The kind of application (i.e. food, feed, cosmetics, medicinal products and devices, technical uses).

# TSE risks of gelatin

In studies of production processes (experimental facilities) with TSE/BSE and with the MBA test as the assay.

- Extensive 'clearance' of infectivity with up to 5-logs (100,000-fold) reduction.
- But the experiments do not demonstrate a complete destruction of all TSE infectivity in a test sample.
- The experiments are limited by the sensitivity of the assay system and the starting titre of the TSE spiked material.

# TSE risks of gelatin

Since processes guaranteed to eliminate all infectivity have not been described for products such as gelatin, tallow, MBM and dicalcium phosphate.

This along with other uncertainties leads the SSC to conclude that careful sourcing of the raw materials and where needed in combination with appropriate processing, remains a key factor in producing safe gelatin.

# BSE risk status of countries

In 1999, the World Organisation for Animal Health (the OIE, recognised by the WTO as the international standard-setting body for animal health and diseases) established a 5-level BSE risk status for countries as:

1. free – (India was here)
2. provisionally free
3. minimum
4. moderate
5. high risk

# BSE risk status of countries

One of the determining factors was the number of cases detected within a 12-month period.

This is not completely reliable.

For this and other reasons as the science is better understood, the OIE categorisation system was changed:

# BSE risk status of countries

## Revised (2007) OIE categorisation

A points targets and surveillance point values were obtained by applying the following factors to a statistical model:

- a) the design prevalence for Type A or Type B surveillance;
- b) a confidence level of 95%;
- c) the pathogenesis, and pathological and clinical expression of BSE:
  - i. sensitivity of diagnostic methods used;
  - ii. relative frequency of expression by age;
  - iii. relative frequency of expression within each subpopulation;
  - iv. interval between pathological change and clinical expression;
- d) demographics of the cattle population, including age distribution;
- e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- f) percentage of infected animals in the cattle population which are not detected.

# BSE risk status of countries

Type A surveillance: Will allow the detection of BSE at one case per 100,000 or greater in the adult cattle population at a confidence level of 95%.

Type B surveillance: ..... one case per 50,000 or greater .....

Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status to confirm the conclusions of the risk assessment.

Type B surveillance may also be carried out by C/Z/Cs of controlled BSE risk status following achievement of the points target using Type A surveillance, to maintain confidence in the conclusion from Type A.



# BSE risk status of countries

<b>Points targets for country, zone or compartment</b>		
<b>Adult cattle population size (24 months and older)</b>	<b>Type A surveillance</b>	<b>Type B surveillance</b>
>1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500

- 1<sup>st</sup> Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)
- 2<sup>nd</sup> Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)
- 3<sup>rd</sup> Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)
- 4<sup>th</sup> Cattle over 36 months of age at routine slaughter

# BSE risk status of countries

<b>Surveillance point values for samples collected from animals in the given subpopulation and age category</b>			
<b>Surveillance subpopulation</b>			
<b>Routine slaughter</b>	<b>Fallen stock</b>	<b>Casualty slaughter</b>	<b>Clinical suspect</b>
<b>Age &gt;1 year and &lt;2years</b>			
0.01	0.2	0.4	N/A
<b>Age &gt;2 years and &lt;4 years (young adult)</b>			
0.1	0.2	0.4	260
<b>Age &gt;4 years and &lt;7 years (middle adult)</b>			
0.2	0.9	1.6	750
<b>Age &gt;7 years and &lt;9 years (older adult)</b>			
0.1	0.4	0.7	220
<b>Age &gt;9 years (aged)</b>			
0.0	0.1	0.2	45
Points remain valid for 7 years (the 95th percentile of the incubation period).			

# BSE risk status of countries

OIE (2007) Categories for BSE disease status are:

- negligible risk
- controlled risk
- undetermined risk

# BSE risk status of countries

Under the OIE criteria, a country can be categorised as negligible risk if it can demonstrate compliance with the recommended safeguards and it has either never had a case of BSE in a domestic animal or any infected domestic animals were born more than 11 years ago.

Countries which are not able to demonstrate they meet, or have not been assessed against, the requirements for negligible risk or controlled risk are placed in the undetermined category.



# BSE risk status of countries

OIE May 2007; Commission Decision 2007/453/EC.

Countries or regions with BSE risk as:-

A - negligible risk	Argentina, Australia, New Zealand, Singapore, Uruguay
B - controlled risk	27 EU Member States, Iceland, Norway, Switzerland
C - undetermined risk	All others, including India

# BSE risk status of countries: Recap

Transitional measures had been taken in Regulation 999/2001 up to July 2007.

OIE have now (2007) developed a simplified and more reliable system for classifying countries for their BSE status.

The new system places particular emphasis on monitoring systems in each country/zone/region.

The safety measures initiated by the EU have made the BSE risk in Europe lower and 'controlled' and this represents an upgrade in status.

For India however this is a downgrading of status from 'BSE-free' to 'undetermined risk'



# Implications of revised BSE status on sourcing for gelatin

Updated opinion on the safety with regard to TSE risks of gelatin. SSC 2003

## **Section C. Sourcing of raw materials for gelatin used in feed, food or cosmetic products...(etc)**

For countries where the presence of one or more cattle clinically or pre-clinically infected with the BSE agent is highly unlikely (geographical **BSE risk level I** )

- sourcing of raw materials from any animal should not present a safety problem with regard to BSE risks.
- sourcing from animals that passed the ante-mortem inspection as fit for human consumption would add additional reassurance.



# Implications of revised BSE status on sourcing for gelatin

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## **Section C. Sourcing of raw materials for gelatin used in feed, food or cosmetic products...(etc)**

For **other countries**, the safest sourcing of the material would in principle be from animals that passed:

- for hides, the *ante-mortem* inspection as fit for human consumption
- for bones, both the *ante-* and *post-mortem* inspection.
- the risk of cross contamination with specified risk materials or potentially contaminated materials should be avoided.



# Implications of revised BSE status on sourcing for gelatin

The change in BSE-status for India from

➤ OIE (1999) BSE Risk level 1 (free)

to

➤ OIE (2007) Level 3 (C) (undetermined risk)

Has implications: Actions could include either to

➤ demonstrate the relevant adherence to Category 3 standards (fit for human consumption)

and/or

➤ to collect and submit information allowing reclassification of the OIE BSE-risk status.

# Requirements concerning ABP in new hygiene regulations

Reg. 852/2004 (Hygiene 1). General provisions for “food waste”: Chapter VI, Annex II

Reg 853/2004 (Hygiene 2). General hygiene requirements for fresh and poultry meats

Reg. 882/2004. Official controls food and feed

Reg 854/2004 (Hygiene 3). Official controls on products of animal origin

# Requirements concerning ABP in new hygiene regulations

Procedures for

- Classification
- Identification
- Separation
- Traceability

# Requirements concerning ABP in new hygiene regulations

Inappropriate separation in the ABP production chain can lead to following hazards:

- contamination with SRM, cat.1 or cat.2 material (microbiological risk)
- contamination with cat.1 or cat.2 material (chemical risk of residues of prohibited substances)
- chemical or physical contamination with waste (plastic, paper, mineral oil.....)

# Requirements concerning ABP in new hygiene regulations

## **Reg. 854/2004 - Sect.I, Chap. I, Ann.I. Auditing tasks - FRESH MEAT**

“.....the official veterinarian is to verify continuous compliance with food operator’s own procedures concerning any collection, transport, storage handling, processing and use or disposal of ABP, including SRM....”

## **Reg. 854/2004 - Sect. I, Ch. II, Ann.I. Inspection tasks - FRESH MEAT**

The OV is to check the removal, separation, marking .. of SRM and ABP.

The OV is to ensure that the food business operator takes all necessary measures to avoid contaminating meat with SRM during slaughter and removal of SRM



# BSE risk status of India and the production of gelatin

Now that the OIE has come up with the criteria for recognition of BSE risk status, India may benefit from assistance in collating information to prepare dossiers so that their BSE status can be assessed.

Some assistance may also be helpful in deciding which inspection measures could play an important role in HACCP analysis (especially with respect to gelatin, ABP and SRM) for sourcing raw materials (bone, hide).



# BSE risk status of India and the production of gelatin

In applications for BSE risk assessment, countries must demonstrate compliance with the following recommended safeguards:

- BSE surveillance has been conducted in accordance with the OIE's BSE guidelines
- an appropriate feed ban is in place
- awareness, education and reporting programs exist
- diagnostic competency is demonstrated
- a risk assessment has been undertaken to guide the design of policies to protect animal and human health.